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ABILIFY® The First Antipsychotic Agent in Japan
Applying for Adjunctive Treatment in Major Depressive Disorder

Otsuka Pharmaceutical Co., Ltd. announced that the company has filed an additional indication for ABILIFY (aripiprazole) in August, as Japan's first antipsychotic agent to be approved for the adjunctive treatment*1 in major depressive disorder.

- Otsuka Pharmaceutical, leading the global research & development in the Central Nervous System domain, has filed for additional indication as adjunctive therapy for major depressive disorder, the first such indication for antipsychotic drugs in Japan
- Patients suffering from depression have increased 2.4-fold in 12 years to 1.4 million; new drug treatment options are desired to encourage patients' social returning, as remission rate for depression is a low 30-40%
- ABILIFY is the world's second best-selling antipsychotic, sold in 60 countries and regions worldwide

Tokyo, Japan, September 3 - Otsuka Pharmaceutical Co., Ltd. (Head Office: Chiyoda-ku, Tokyo, Japan; President: Taro Iwamoto) announced that the company has filed an additional indication for ABILIFY (aripiprazole) in August, as Japan's first antipsychotic agent to be approved for the adjunctive treatment*1 in major depressive disorder.

Depression is a common mental disorder in Japan, experienced by about 1 in 15 people during their lifetime. The prevalence of depression in Japanese people is said to be at a rate of 6.3% during lifetime, and patient numbers have increased 2.4-fold over the last 12 years, reaching 1.4 million in 2008.

Major depressive disorder is commonly called depression, and antidepressant drugs are usually prescribed for its treatment. Patients' symptoms are said to improve by 50-60% when treated by antidepressant drugs, and the percentage of patients achieving remission by antidepressant drug is said to be 30-40%. New drug treatment options are desired for the alleviation of depressive disorders, as many patients still find difficulties even when treated with existing antidepressant drugs.

Otsuka Pharmaceutical conducted a Phase III clinical trial aiming to gain approval for ABILIFY as adjunctive therapy in major depressive disorder, in Japan. Based on results of these trials obtained in April 2012, Otsuka Pharmaceutical have filed application in four months, which is considerably a short period of time for filing, as we aim to deliver treatment options to patients and clinicians as quickly as possible.

ABILIFY is the world's first antipsychotic drug with a dopamine D2 receptor partial agonist mechanism, which was primarily sold in the United States in 2002, and is now available in over 60 countries and regions worldwide.

ABILIFY obtained the world's first indication for adjunctive therapy in major depressive disorder in the United States in 2007, and since then has offered unique value transcending the limits of conventional antipsychotic drugs. As a result, ABILIFY has grown to become the second best-selling^{*2} antipsychotic drug in the world. Otsuka Pharmaceutical will continue researching in CNS areas, creating and delivering innovative healthcare solutions for patients across the world.

*1: The filing is being conducted for adjunct therapy in which ABILIFY is added to and used alongside existing treatment when sufficient effect is not obtained with antidepressant drugs(SSRI, SNRI).

*2: Source: Research by Cegecim Strategic Data K.K.